U.S. Department of Agriculture

Office of Inspector General
Midwest Region

Audit Report

Review of Pathogen Reduction Enforcement Program Sampling Procedures

Report No. 24601- 0007-Ch
September 2006

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

DATE: September 28, 2006

REPLY TO
ATTN OF: 24601-0007-Ch

TO: Barbara J. Masters, D.V.M
Administrator
Food Safety and Inspection Service

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement and Review

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Review of Pathogen Reduction Enforcement Program Sampling Procedures

This report presents the results of our audit of the Food Safety and Inspection Service's (FSIS) pathogen reduction efforts. Our audit evaluated the effectiveness of FSIS' process for scheduling and conducting microbiological testing of meat and poultry products.

The FSIS response to the official draft report is included in exhibit D with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations sections of the report. Based on the response, we have reached management decisions on Recommendations 1, 2, 3, 4 and 6. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

Management decision has not been reached for Recommendation 5. Management decision can be reached on this recommendation once you have provided the additional information outlined in the report section, OIG Position.

In accordance with Departmental Regulation 1720-1, please provide a reply within 60 days describing the corrective action taken and planned, including timeframes for their implementation. Please note that the regulation requires that management decisions be reached on all recommendations within a maximum of 6 months from report issuance.

We appreciate the courtesies and cooperation extended to the auditors by your staff during the audit.

Attachment

Executive Summary

Review of Pathogen Reduction Enforcement Program Sampling Procedures (Audit Report No. 24601-0007-Ch)

Results in Brief

The Pathogen Reduction Enforcement Program (PREP) is a database and monitoring system maintained by FSIS' Office of Public Health and Science (OPHS). The system is used to support FSIS' pathogen reduction efforts by scheduling microbiological product sampling at FSIS-inspected meat and poultry establishments, and generating automated reports that allow FSIS managers to monitor both the sampling process and the results of laboratory tests. PREP supports the science-based Hazard Analysis and Critical Control Point (HACCP) system as a tool for preventing and controlling contamination through *Salmonella* testing. In addition, it is used to identify selected products for testing of the adulterants *E. coli* O157:H7 and *Listeria monocytogenes*. The PREP system became operational in 2001, and has been a valuable tool in FSIS' pathogen reduction efforts.

We found that in the testing programs for the adulterants *E. coli* 0157:H7 and *Listeria monocytogenes*, FSIS had developed procedures to transfer establishment data from the Performance Based Inspection System (PBIS)[1] to PREP (two separate systems), and was selecting the identified establishments for testing within reasonable timeframes. However, we found that controls still need to be materially strengthened within the *Salmonella* testing program to ensure that all establishments are included as required in microbiological testing programs. We found a significant number of establishments that were excluded from the *Salmonella* sampling database because of ineffective controls to identify eligible establishments and also because district office personnel did not fully understand the process for including the establishments in the database. At the district we visited, 28 percent of the establishments that should have been subject to *Salmonella* testing were excluded from the sampling database. This problem was particularly apparent at establishments inspected under Federal-State Cooperative Programs (Talmadge-Aiken establishments) in the one State we visited. The State supervisors responsible for program oversight at these establishments were not provided with the eligibility reports that could have allowed them to identify establishments that needed to be included in the sampling database.

[1] "The Performance Based Inspection System (PBIS) was implemented in 1989 to provide a method of scheduling inspection tasks and recording their results. Each establishment has a PBIS establishment profile, maintained by the FSIS inspector, which identifies the species slaughtered and/or processed as well as other key data pertaining to the establishment."

Although the 2002 ConAgra recall highlighted the risks of exempting establishments from microbiological testing by FSIS field laboratories, we noted that some establishments continue to be excluded from product testing. Specifically, we found that because of the time needed to collect and test the required number of samples to complete a sampling set under the PR/HACCP *Salmonella* testing program, establishments whose slaughter or processing activity falls below a specific threshold are not subject to product testing. Likewise, establishments that produce non-intact beef products that do not meet the standard of identity of Section 9, Code of Federal Regulations (CFR) 319.15 (a), (b), or (c) such as raw ground beef sausages and meatballs, are excluded from testing. Agency officials stated that their policy was based on their assessment of the risk factors involved in different types of ground beef products, including the expectation that consumers are more likely to fully cook these products than tested products such as bulk ground beef and hamburger patties. However, the agency could not provide documentation to support these determinations. As a result, there is a reduced level of assurance that products from establishments which produce such products will be free of this pathogen.

Recommendations In Brief

We recommended that FSIS strengthen its procedures to ensure that all establishments subject to *Salmonella* testing are identified. In addition, we recommended that modifications be made to the PBIS to allow PREP to draw establishment information directly from that system rather than depending on manual updates. We also recommended that FSIS develop a risk assessment to support its policy for excluding low-volume establishments from *Salmonella* testing or conduct testing in all plants, and that the agency obtain scientific advice to evaluate whether its policy of not testing certain raw ground beef products for *E. coli* O157:H7 contamination should be continued.

Agency Response

In their response dated September 26, 2006, FSIS officials generally agreed with the findings and recommendations contained in this report. We have incorporated applicable portions of FSIS' response, along with our position, in the Findings and Recommendations section of this report. The agency's response is included in its entirety as exhibit D of the report.

OIG Position

We agree with FSIS officials' response to the recommendations and have reached management decisions on Recommendations 1, 2, 3, 4, and 6. Management decision has not been reached for Recommendation 5. Management decision can be reached on this recommendation once we receive the information specified in the OIG Position section for this recommendation.

Abbreviations Used in This Report

AMR	Advanced Meat Recovery (Systems)
eADRS	Electronic Animal Disposition Reporting System
E. coli O157:H7	*Escherichia coli* O157:H7
FSIS	Food Safety and Inspection Service
HACCP	Hazard Analysis and Critical Control Point (System)
IPPS	In-Plant Performance System
IT	Information Technology
OFO	Office of Field Operations
OPHS	Office of Public Health and Science
OPPED	Office of Policy, Program and Employee Development
PBIS	Performance Based Inspection System
PREP	Pathogen Reduction Enforcement Program
PR/HACCP	Pathogen Reduction/Hazard Analysis and Critical Control Point (System)
RTE	Ready-to-Eat

Table of Contents

Background and Objectives

Background

The Food Safety and Inspection Service (FSIS) was established by the Secretary of Agriculture on June 17, 1981, to ensure that the Nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. Over 7,600 full-time FSIS inspectors monitor the slaughter and processing of meat and poultry products at approximately 6,000 establishments nationwide. FSIS inspectors take microbiological samples for the various testing programs based on instructions from FSIS' Office of Public Health and Science (OPHS), which manages the various testing programs within FSIS.

In 1996, FSIS issued its landmark rule, Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) System, which replaced the old method of inspection with a system based on science and laboratory diagnostics. The new science-based system was designed to improve food safety and make better use of agency resources. In addition, the final rule established pathogen reduction performance standards for *Salmonella* in raw meat and poultry products. To improve the effectiveness and efficiency of the laboratory testing programs, FSIS instituted the Pathogen Reduction Enforcement Program (PREP) system in 2001. The PREP system contains databases which record key information on all meat and poultry establishments subject to product testing under three different programs.

- The PR/HACCP *Salmonella* program supports the HACCP system by testing products for the presence of *Salmonella*. *Salmonella* was selected because it can be detected with modern microbiology techniques and is present in varying degrees in all major species. In addition, the health and safety concerns stemming from *Salmonella* contamination in products marketed to consumers have become of increasing concern to both the Department and the public. This testing is performed on all products for which *Salmonella* testing standards have been developed and incorporated into the regulations. These include both slaughtered and processed beef and chicken. In addition, there are standards for slaughtered swine and processed turkey. Product testing for *Salmonella* is performed in "sets" of between 51 and 82[2] individual sample tests. As of November 2005, the PREP system recorded 1,481 establishments nationwide whose products were subject to *Salmonella* testing. In 2005 FSIS field laboratories tested 40,714 initial samples for *Salmonella,* with additional testing performed in cases where followup was required.

- The MT03 program tests raw ground beef products for the presence of the pathogen *E. coli* O157:H7. Since this pathogen is classed as an adulterant

[2] 9 CFR 381.94 (b) (1), 9 CFR 310.25 (b) (1)

and can cause serious illness or death if ingested with inadequately cooked product, a single confirmed positive test result is sufficient to warrant immediate action by FSIS, including the prompt recall of any product believed to be contaminated. For this testing program, the PREP system draws its "sampling frame" of eligible establishments directly from the plant profiles which individual establishment inspectors maintain as part of the Performance-Based Inspection System (PBIS). As of February 2006, there were 1,653 establishments nationwide that were subject to *E. coli* O157:H7 testing, and during 2005 the field laboratories performed 10,976 tests.

- The Ready-To-Eat (RTE) sampling program tests processed meat and poultry products that can be eaten as-is by consumers without additional cooking. This testing program looks for the presence of *Listeria monocytogenes*, a dangerous pathogen which like *E. coli* O157:H7 is classified as an adulterant in meat and poultry products. Like the MT03 sampling frame, the RTE sampling frame is drawn directly from the PBIS Plant Profiles, which are electronically updated into PREP on a monthly basis. In February 2006, there were 2,434 establishments in the RTE sampling frame, and the agency performed 16,000 laboratory tests for *Listeria monocytogenes* in 2005.

In addition to scheduling product tests, PREP also maintains information on test results and the disposition of product sampling requests. The system generates a number of standard reports that are provided to the district offices on a periodic basis to allow them to monitor various aspects of the testing programs. These reports include the *Salmonella* Performance Standards Testing Eligibility Report, which districts use to ensure the completeness of the manually-updated PR/HACCP *Salmonella* sampling frame, and the Non-Responder Report which lists establishments where FSIS inspectors have failed to respond to requests for product samples. The system also tracks other information, such as the last date that a particular establishment was scheduled for product testing or actually had a sample analyzed. Although not generated in report format on a routine basis, this information can be accessed through ad hoc reports by trained personnel such as those in FSIS' Data Systems Management Division.

Prior OIG audits,[3] performed before the PREP system became operational, disclosed that sampling frames were incomplete, and that as a result not all eligible establishments were in fact subject to testing. In addition, our earlier audit work disclosed that FSIS did not track instances in which FSIS establishment inspectors failed to respond to OPHS requests for product samples to be tested for *Salmonella, E. coli* O157:H7, or *Listeria*

[3] Audit Report Nos. 24601-0001-CH, "Laboratory Testing of Meat and Poultry Products," June 2000; and 24001-0004-AT, "Followup Audit on the Inspector General's Food Safety Initiative of Fiscal Year 2000," September 2004

monocytogenes. In their responses to our earlier recommendations in this area, FSIS officials cited the PREP system as a major component in addressing the reported deficiencies.

Objectives

The objective of this audit was to evaluate the effectiveness of FSIS' process for scheduling and conducting microbiological testing of meat and poultry products. Specifically, we determined whether: (1) FSIS has effective controls to ensure that all eligible meat and poultry establishments are included in the appropriate sampling database; (2) changes in an establishment's operational status or type of product are timely reflected in the database; and (3) processes exist to ensure that all establishments are selected for testing within a reasonable amount of time.

Findings and Recommendations

Section 1. Microbiological Testing Programs Do Not Include All Required Establishments

Controls need to be materially strengthened to ensure that all required establishments are included in microbiological testing programs conducted by FSIS. We found a significant number of establishments that were excluded from the *Salmonella* sampling database maintained in the PREP system, due to ineffective controls and to a system for manual followup and input that was not fully understood by FSIS officials at the district office level. At one district, 28 percent of the establishments subject to *Salmonella* testing were not included in the database. This problem was particularly noticeable in State-inspected establishments that were subject to PREP testing under Federal-State Cooperative Agreements. A key tracking report was not provided to supervisors in these establishments until this situation was identified by our audit. On a nationwide basis, we identified a large number of establishments that may have been inadvertently left out of the sampling process.

PREP is an information system that schedules samples and tracks test results of *Salmonella* sample sets for the Pathogen Reduction/Hazard Analysis and Critical Control Point (PR/HACCP) program. PREP also schedules samples for the MT03 (*E. coli* O157:H7) and RTE (*Listeria monocytogenes)* testing programs. OPHS provides microbiological, chemical, and toxicological expertise, leadership, and quality assurance and control for the agency. OPHS also manages laboratory activities including analyses of official samples obtained from meat and poultry establishments under a variety of testing programs. FSIS uses PREP to select establishments for product testing. The system contains separate listings of establishments, referred to as "sampling frames," which categorize establishments by the type of testing they are subject to. However, unlike the MT03 and RTE sampling frames which drew their information directly from the PBIS Plant Profiles maintained by the establishment inspectors, OPHS relied upon field inspectors to inform them of establishments needing to be tested under PR/HACCP *Salmonella*.

Finding 1 — *Salmonella* Testing Frame Significantly Understated

Our review in one district found that the PREP sampling frame for PR/HACCP *Salmonella,* which identified 99 establishments as being eligible for testing, was understated by 39 establishments (28 percent). This occurred because FSIS had not established an automated control to assist in the identification of such establishments. Instead, they relied upon field inspectors and frontline supervisors to inform them of establishments which needed to be included in the sampling frame. However, personnel at the district level were not always aware of how the system was intended to work, or did not understand their role in it. As a result, the 39 establishments we identified were not being tested for *Salmonella*, thus reducing the assurance that FSIS would become aware of such contamination.

On July 25, 1996, FSIS published its final rule on Pathogen Reduction and Hazard Analysis and Critical Control Point Systems (PR/HACCP), which established new requirements for all meat and poultry products to improve food safety. Under HACCP, all slaughter and processing establishments are required to adopt the HACCP process controls to prevent food safety hazards. To verify that HACCP systems are effective in controlling contamination of raw product with harmful bacteria, the rule sets pathogen reduction performance standards for *Salmonella* that establishments must meet if they produce certain kinds of products. Establishments affected by the *Salmonella* testing requirement – under which product samples are obtained by FSIS establishment inspectors and tested by FSIS field laboratories – include slaughtering establishments for cattle, swine, and (chicken) broilers, and also establishments that process raw ground beef, chicken, and turkey. As of June 2006, turkey slaughtering establishments were also incorporated into the sampling program to address public concerns over the safety of this product.

Qualifying establishments are listed in a "sampling frame" that is maintained by FSIS as an electronic database in its PREP system. FSIS uses this sampling frame each month to select the establishments whose products will be tested for *Salmonella* contamination. An establishment must be included in the sampling frame in order to be selected for testing. We found that, unlike the other two microbiological testing programs that FSIS operates (*E. coli* O157:H7 testing for raw ground beef and *Listeria monocytogenes* testing for Ready-to-Eat products), the PR/HACCP sampling frame is not automatically updated directly from PBIS. This is because the PBIS establishment profiles do not contain data on production levels and operating schedules (see Finding 3) that determines which establishments need to be tested. Instead, this sampling frame must be kept up-to-date manually and is dependent upon FSIS field personnel to identify the eligible establishments within their districts and report them for inclusion.

Every 6 months, FSIS uses the PREP system to generate the *Salmonella* Performance Standards Testing Eligibility Report. This report is sent electronically to each frontline supervisor (responsible for visiting inspected establishments and overseeing the activities of FSIS inspectors) and district manager. It lists every establishment under the district's jurisdiction that, as of the date of the report, was included in the PR/HACCP *Salmonella* sampling frame.

The instructions at the top of each report provide that:

> . . . District managers and inspection personnel should review plant production activities for all plants to determine if a plant is subject to *Salmonella* Performance Standard requirements for one or more classes of product. If you are aware that a plant under your jurisdiction is producing a product that is subject to *Salmonella* Performance Standard testing and the plant is not on this report, you must notify OPHS by sending a reply to this message in Outlook.

The instructions also include the production thresholds below which an establishment is exempt from *Salmonella* testing (see Finding 2).

The district analyst and the managers at the district office we visited stated that, based on their understanding, all of the PREP sampling frames were updated directly from the PBIS Plant Profile that each FSIS establishment inspector maintains on an ongoing basis. This profile contains information on the types of products (i.e., beef, chicken) and on the type of processes that each FSIS-inspected establishment uses (slaughter, grinding of raw product, processing of Ready-to-Eat products, etc.). Thus, district officials believed that a qualifying establishment would be automatically added to the sampling frame as long as the PBIS Plant Profile contained correct and complete information on the establishment's products and operations. District officials informed us that they instructed their frontline supervisors to ensure that establishment inspectors update the Plant Profiles in PBIS.

However, as noted earlier, the PR/HACCP *Salmonella* sampling frame is not drawn directly from the PBIS Plant Profile because FSIS policy excludes any establishment that slaughters fewer than a certain number of animals or birds, or processes fewer than 26 days per year. This information is not contained in the PBIS Plant Profile. The district officials were not aware of this, however, until FSIS Headquarters officials informed them of the policy following our discussions. In interviews with the frontline supervisors, we found that some of them likewise believed that the sampling frame was updated automatically based on the Plant Profile and thus did not use the semiannual *Salmonella* Performance Standards Testing Eligibility Report.

As of November 2005, the PR/HACCP sampling frame listed 1,481 establishments nationwide. To determine whether the sampling frame contained all of the qualifying establishments that needed to be tested for *Salmonella*, we obtained a PBIS listing of all FSIS-inspected establishments within the jurisdiction of the district we visited, and identified those whose products should have made them eligible for inclusion in the sampling frame. (Note that we relied on the accuracy of PBIS data, since performing tests of that system was not part of the scope of this audit.) For the slaughter establishments, we were able to eliminate those whose volume of activity (fewer than 500 red meat carcasses slaughtered on less than 100 days, or fewer than 20,000 birds) exempted them under FSIS policy using the Electronic Animal Disposition Reporting System (eADRS). No equivalent report existed for processing establishments, so we could not determine which of those did, or did not, qualify based on their level of activity. We found that a total of 174 establishments in the selected district appeared eligible for *Salmonella* testing; however, the sampling frame listed only 99 of these. We requested that the district review the remaining 75 establishments to determine whether they met the criteria that would require them to be tested for *Salmonella*.

District officials responded that, as a result of their followup, they determined that 37 of the 75 establishments needed to be added to the sampling frame. In addition, the district identified 2 other establishments that needed to be added to the sampling frame, for a total of 39 (see exhibit B for a profile of these establishments). The remainder, all processing establishments, were determined ineligible because they operated fewer than the 26-days-per-year threshold or because their products were not covered under FSIS' testing standards.

Because of this large discrepancy, we performed the same review for the remaining districts, and nationwide we found that, excluding the district already reviewed, the PR/HACCP sampling frame listed 1,382 establishments. Using PBIS and eADRS, we identified an additional 790 establishments (see exhibit A) that appeared eligible for the sampling program. Profiles of these establishments are presented in exhibit C. This information was provided to FSIS, so that any necessary followup could be performed. Although some of the 790 establishments will likely be excluded because their processing is too infrequent, it appears that the 1,481 establishments in the sampling frame nationwide (including the selected district) could be significantly understated.

By contrast, we found that the other sampling frames – which did not rely on field personnel to identify establishments that needed to be included, but instead got their data from the Establishment Profiles in PBIS – did not have this deficiency. Although we recognize that additional data elements are needed to determine eligibility for this sampling frame as opposed to those

for *E. coli* O157:H7 and *Listeria monocytogenes* testing, the number of excluded establishments noted above indicates that in the long term, FSIS needs to develop an automated means of identifying establishments for inclusion in the *Salmonella* sampling frame. This could, in part, be done by making better use of the information in eADRS. In the interim, agency officials need to take steps to ensure that district managers and frontline supervisors clearly understand their responsibilities for following up on the *Salmonella* Performance Standards Testing Eligibility Report and ensuring that all eligible establishments are reported to FSIS for inclusion in the sampling frame.

Recommendation 1

Issue guidance to more clearly state the responsibilities of field personnel in assuring the *Salmonella* sampling frame includes all establishments eligible for testing.

Agency Response

FSIS officials stated that the Office of Policy, Program, and Employee Development (OPPED) will develop an FSIS Notice that gives explicit instructions to District Managers to update the PREP Salmonella sampling frame. Eligibility requirements for the *Salmonella* sampling frame will be included and will reflect the recently published "FSIS Scheduling Criteria for *Salmonella* Sets in Raw Classes of Product" which outlines agency policy to allocate sampling within classes of raw product and is based on agency data of variability of process control at individual establishments. The expected completion date is December 2006.

OIG Position

We accept FSIS' management decision. Final action can be reached upon issuance of the proposed notice.

Recommendation 2

Modify PBIS to incorporate the codings necessary to identify establishments requiring *Salmonella* testing similar to those presently used for the *E. coli* O157:H7 and *Listeria monocytogenes* testing programs.

Agency Response

FSIS officials stated that the PBIS is being modified to update the *Salmonella* sampling frame. The response further stated that an FSIS notice has been drafted to inform the districts that they will no longer receive the eligibility report, and that the *Salmonella* sampling frame will be derived in part, from

electronic PBIS data. Instructions are provided for identifying new establishments or establishments that begin making an eligible product, and getting them added to the frame. They expect this action to be completed in March 2007.

OIG Position

We accept FSIS' management decision. Final action can be reached upon completion of the modification and issuance of the notice.

Recommendation 3

Use eADRS to the extent necessary to ensure that all establishments eligible for *Salmonella* testing are included in the sampling frame.

Agency Response

FSIS officials stated that the frames will be derived, in part, from eADRS data. The agency began using eADRS data to identify establishments slaughtering species for which there is a performance standard or guideline in May 2005. They expect completion in March 2007.

OIG Position

We accept FSIS' management decision. Final action can be reached when this action is completed in conjunction with the PBIS modification.

Finding 2 — In At Least One District, Talmadge-Aiken Establishments Were Excluded From PR/HACCP *Salmonella* Sampling

In our visit to one district, we found that establishments inspected by State employees under Federal-State Cooperative Agreements (Talmadge-Aiken establishments) were less likely than FSIS-inspected establishments to be included in the PR/HACCP testing program. This occurred because neither OPHS nor the Office of Field Operations (OFO) had provided specific guidance on how these establishments were to be covered under the existing system for identifying eligible establishments. As a result, we found a notable disparity in the number of slaughter establishments that were left out of the sampling frame. Prior to our review, only 31 percent of the Talmadge-Aiken establishments in the district had been included in the PR/HACCP *Salmonella* sampling frame, as compared to 81 percent of FSIS-inspected establishments.

"Talmadge-Aiken plants," are authorized under the Talmadge-Aiken Act of 1962. The approximately 350 meat and poultry establishments that operate under this program, located in 9 States, are considered Federally-inspected establishments but are in fact inspected by State employees. Unlike State-inspected establishments, these establishments can market their products interstate and are governed by FSIS regulations.

The district office we visited (District 50) covers 3 States, one of which (Illinois) had 8 Talmadge-Aiken establishments listed in the PR/HACCP *Salmonella* sampling frame; these establishments represented about 8 percent of the 99 establishments in the sampling frame for this district. To determine whether establishments producing products subject to microbiological testing under the PR/HACCP *Salmonella* program were included in the sampling frame, we reviewed eADRS. This system allowed us to determine whether slaughter establishments produced a sufficient volume of product to be subject to testing under current FSIS policy. This review identified 10 slaughter establishments that were not in the PR/HACCP *Salmonella* sampling frame, even though they qualified both in terms of the type of product produced and the level of production. Of these, 9 were Talmadge-Aiken establishments.

At our request, the district office verified that 37 of the 75 establishments we questioned should have been included in the sampling frame. Of the 37 establishments, 16 were Talmadge-Aiken establishments. The district also identified two additional Talmadge-Aiken establishments that needed to be included in the sampling frame. Thus, of 26 Talmadge-Aiken establishments that should have been included in the PR/HACCP sampling frame, 18 (69 percent) had been omitted. By contrast, 19 percent (21 of 112) of the establishments inspected directly by FSIS were omitted.

FSIS frontline supervisors, who are responsible for ensuring that eligible establishments are included in the *Salmonella* testing program, are provided the *Salmonella* Performance Standards Testing Eligibility Report in electronic format when it is issued twice a year. However, in our interview with the Illinois official who oversees inspection operations at the Talmadge-Aiken establishments, we found that he did not have access to FSIS' system and therefore did not get the report. As a result, the State supervisors who perform equivalent functions to the FSIS frontline supervisors did not have the necessary information to identify establishments that should have been placed in the sampling frame.

We discussed this with an FSIS district official, who concurred that the State employees need to have access to this system in order to be effective in identifying establishments whose products need to be tested for *Salmonella*. As a result of our audit, the district office provided State supervisors with the necessary system access to receive the *Salmonella* Performance Standards Testing Eligibility Report and to electronically report establishments that need to be added, as FSIS frontline supervisors do. District management stated that they had not received any guidance from FSIS Headquarters on what procedures should be followed to ensure Talmadge-Aiken establishments are included in the sampling frame.

An FSIS Headquarters official confirmed that FSIS has not provided guidance, saying that managers in each district were allowed to deal with the Talmadge-Aiken establishments in their own manner. However, the fact that District 50 had not implemented such a process until the time of our audit, as well as the large percentage of Talmadge-Aiken establishments that were not included in the sampling frame, indicates the need for FSIS Headquarters to provide written guidance to the districts to ensure these conditions are not occurring on a nationwide basis.

Recommendation 4

Provide written procedures to all district offices to ensure that processes for identifying establishments that need to be tested for *Salmonella* are applied to Talmadge-Aiken establishments.

Agency Response

FSIS officials stated that OPPED will develop an FSIS Notice that gives explicit instructions to District Managers to update the PREP *Salmonella* sampling frame. They expect this action to be completed in December 2006.

OIG Position

We accept FSIS' management decision. Final action can be reached upon issuance of the notice.

Following the massive ConAgra recall of ground beef products in 2002, FSIS officials revoked an earlier policy that exempted some establishments which would otherwise have been subject to product testing for *E. coli* O157:H7 under the MT03 testing program. However, we noted that some exclusions continue to exist, and establishments that fall under these are not subject to product testing. FSIS could not provide scientific support and/or risk assessments to support these exclusions from testing. We found that because of the time needed to collect and test the required number of samples to complete a sampling set under the PR/HACCP *Salmonella* testing program, establishments whose slaughter or processing activity falls below a specific threshold are not subject to product testing. Likewise, establishments that produce non-intact beef products that do not meet the standard of identity of 9 CFR 319.15 (a), (b), or (c) are excluded from *E. coli* O157:H7 testing. FSIS officials stated that certain raw ground beef products are excluded because they involve less risk to the public. However, because of these exclusions, there is a reduced level of assurance that products produced at these establishments will be free of dangerous pathogens.

Finding 3 FSIS Excludes Small and Low-Volume Establishments From Its *Salmonella* Testing Program

The FSIS *Salmonella* testing program focuses on large establishments, those slaughtering more than 500 meat animals or 20,000 birds per year, and processing establishments that operate on 26 or more days per year. An FSIS official stated that these thresholds were set so that the sample sets required for *Salmonella* testing could be completed within a reasonable timeframe, but could not provide documentation of the specific factors that went into their determination. However, excluding smaller slaughter or processing establishments from its *Salmonella* testing program could also increase the risk that *Salmonella* contamination or sanitation problems at these smaller establishments could go undetected.

FSIS, in its 1996 rule on Pathogen Reduction and Hazard Analysis and Critical Control Point Systems (PR/HACCP), established requirements intended to improve food safety at all meat and poultry slaughter and processing establishments. To ensure that the HACCP programs at each establishment are effective in maintaining acceptable sanitation standards and preventing the contamination of products by harmful microbiological organisms, FSIS created pathogen reduction performance standards for a number of commonly-marketed meat and poultry products including broilers (young chickens, Guineas, etc.), steers, heifers, bulls, cows, and hogs. Any

establishment producing one of these products is required to submit product samples for *Salmonella* testing by one of the FSIS field laboratories. *Salmonella* was selected for this testing program because its presence is considered a sign of overall sanitation problems at an establishment, which could result in public health issues. Unlike *E. coli* O157:H7 or *Listeria monocytogenes*, however, a single positive test result for *Salmonella* is not considered as proof of a significant sanitation problem or a lack of process controls. Therefore, *Salmonella* testing is done in "sets" of between 51 to 82 product samples. The regulations define the number of "positive" *Salmonella* test results for each product that would warrant enforcement action by FSIS.

However, because the time needed to complete the sampling "sets" depended on the activity level of the establishment being tested – with establishments that seldom slaughter or process product taking longer because of product availability issues – FSIS established activity thresholds as part of its sampling eligibility determination for each establishment. As stated in the *Salmonella* Performance Standards Testing Eligibility Report that OPHS provides to each district twice a year, an "Infrequent Producer" is defined as a establishment that:

- Produces raw ground beef less than 26 times per year;
- Slaughters fewer than 500 red meat carcasses on less than 100 different days per year; or
- Slaughters fewer than 20,000 young chickens per year.

An FSIS official stated that the 26-times-per-year threshold is interpreted as meaning 26 different days per year, and is applied to any non-slaughter operation (i.e., a processing establishment). The 500-per-year threshold also applies to hogs, and the 20,000-per-year threshold applies to any type of bird (except for turkeys, which were added to the program in June 2006 and are tested only if the establishment produces on 100 or more days per year) covered by the testing program. The official stated that if an establishment slaughters or processes less frequently than described in the standards, an excessive amount of time is required to collect the number of samples needed to complete a sample set. As a result, FSIS excluded such establishments from the testing program and concentrated its efforts on the larger and more frequently-operating establishments.

However, FSIS officials could not provide us with any documentation supporting their determination of what establishments to exclude. Nor did they have studies that documented that the risk associated with products produced by smaller establishments was less than that of larger establishments. As a result, FSIS cannot demonstrate that HACCP systems operating at small or low-volume establishments are low-risk for pathogen contamination.

Because the PBIS Plant Profiles do not contain data on an establishment's level of activity (see Finding 1), the number of establishments nationwide that would be excluded from the PR/HACCP *Salmonella* testing program cannot be precisely determined. However, in the district we visited, we found that out of 75 establishments we identified as potentially meeting FSIS criteria for sampling (based on the type of product shown as being produced per the PBIS Plant Profile), 12 (16 percent) were determined by the district to be infrequent producers and therefore exempt. Nationwide, we identified an additional 790 establishments (see exhibit A) that have not been included in the sampling frame for PR/HACCP *Salmonella*, so it is possible that a similar percentage of these would also be excluded under FSIS policy.

Product produced in smaller establishments is consumed by a public knowing that FSIS conducts microbiological testing to ensure the wholesomeness and safety of meat and poultry food products. Therefore, FSIS needs to develop a risk assessment supporting its testing policy or conduct testing in all plants.

Recommendation 5

Develop a risk assessment to support the agency's policy in excluding establishments from *Salmonella* testing or conduct testing in all plants.

Agency Response

FSIS officials stated that product produced by plants not included in the *Salmonella* testing program represents a fraction of a percent of consumer exposure to *Salmonella* from raw meat and poultry. They believe consumer exposure is minimal from the establishments which are not tested and did not agree to perform a risk assessment. In the risk-based system approach that FSIS is developing, exposure of food safety hazards to the public is related to production volume and this is where they will place their emphasis.

OIG Position

We cannot reach management decision because FSIS officials have not provided support for their position that risk is based solely on production volume. In fact, FSIS' own data on non-compliance reports for sanitation demonstrate that, on average, small establishments have sanitation deficiencies at a rate comparable to larger establishments, the only difference being that less product is distributed to the public. To reach management decision, FSIS officials need to provide the recommended risk assessment or else provide for at least a minimal level of testing at smaller establishments.

Finding 4 — Some Raw Ground Beef Products Are Excluded From *E. coli* O157:H7 Testing

Although FSIS' testing program for the pathogen *E. coli* O157:H7 is intended to ensure the safety of raw ground beef products marketed to the public, we found that some ground beef products such as meatballs and sausages are not tested because of an agency determination that they were of sufficiently low risk that testing was not warranted. As a result, there is reduced assurance that establishments that produce these products are free from contamination by *E. coli* O157:H7.

When *E. coli* O157:H7 was declared an adulterant in raw ground beef products in 1994, FSIS began testing raw ground beef for this pathogen at slaughter and processing establishments. However, when the testing program was announced, the Texas Food Industry Association filed a case in Federal Court against the Secretary of Agriculture to prevent this testing. The plaintiffs, as noted in the court's ruling dated December 13, 1994, contended among other things that FSIS and USDA had exceeded their statutory authority in declaring *E. coli* O157:H7 an adulterant (as opposed to pathogens such as *Salmonella*, which are not classified as adulterants). This contention was based on the argument that "*E. coli* contaminated ground beef is not adulterated because it is only injurious to health if improperly cooked."

The court disagreed with this contention and ruled in the Department's favor, stating that:

> However, unlike other pathogens, it is not "proper" cooking but "thorough" cooking that is necessary to protect consumers from *E. coli*. The evidence submitted by defendants indicates that many Americans consider ground beef to be properly cooked rare, medium rare, or medium . . . therefore, *E. coli* is a substance that renders "injurious to health" what many Americans believe to be properly cooked ground beef. Based on this evidence, the Court finds that *E. coli* fits the definition of an adulterant under the [Federal Meat Inspection] Act.[4]

During our audit, we noted that FSIS inspectors in numerous meat establishments repeatedly responded to OPHS requests for raw ground beef product samples under the MT03 (*E. coli* O157:H7) testing program with the code that showed that the product was not produced, even though their PBIS Plant Profiles continued to reflect raw ground beef HACCP processes from month to month. Our fieldwork included visits to establishments that were listed in the MT03 sampling frame, and we found that in some cases, the

[4] Title 21 USC, Chapter 12, Meat Inspection, the Federal Meat Inspection Act of 1906.

establishments were producing either "mixed" products containing raw ground pork as well as beef, raw ground beef products formed into meatballs, or other products clearly not intended for use as hamburgers or hamburger patties. The establishment inspectors and frontline supervisors stated that they had been instructed not to send in samples of such products.

FSIS officials confirmed this, stating that the agency's policy was to limit the testing program to raw ground beef or veal products clearly intended for use as hamburger patties or which otherwise met the standard of 9 CFR 319.15 (a), (b), or (c). They stated that products such as raw ground beef meatballs and sausages, as well as raw ground beef used in mixed-meat or spiced products, were excluded. Officials stated that, among other factors, consumers were more likely to fully cook these products (as referenced in the Federal Court ruling) than would be the case with hamburgers or other products that might be made from bulk ground beef marketed to the public.

Officials of the Data Systems Management Division stated that establishments producing "excluded" raw ground beef products continued to appear in the MT03 sampling frame because PREP automatically identifies any establishment whose PBIS Plant Profile carries the code "03B Ground Beef" as eligible for testing. The 03B code cannot be removed because it is this code that signals PBIS to schedule tasks for the establishment inspectors related to ground beef production. They noted that it would be preferable to send extra testing kits than to take a chance on having PBIS fail to schedule these tasks, or to miss sending *E. coli* O157:H7 test kits to establishments that should be properly included in the testing program.

Based in part on their discussions with OIG, FSIS' OPPED issued FSIS Notice 80-05 on December 5, 2005. This notice announced the addition of a "check box" to the PBIS Plant Profile, which would give the inspector the ability to identify whether an establishment's products met the standards of identity for *E. coli* O157:H7 testing under 9 CFR 319.15 (a), (b), or (c).[5] Once this feature becomes fully operational, it would be necessary for an inspector to fill in the check box before PBIS would identify the establishment as subject to testing under the MT03 sampling frame. Any establishment for which this box is not checked would be disregarded by the system when it refreshes the MT03 sampling frame each month. The notice also restated the types of product that are to be included or excluded from the testing program. Products specifically excluded include "any raw ground beef mixed with other species (pork or poultry); raw product comprised only of beef from advanced meat recovery (AMR) systems; fresh beef sausage, Italian sausage, and other raw beef sausage products; and raw ground beef meatballs."

[5] Title 9-Animals And Animal Products, Chapter III-FSIS, Department of Agriculture, Part 319 Standards of Identity or Composition, Section 319.15 Miscellaneous Products.

The procedures, such as the "check box" feature mentioned in the FSIS notice, does not address the question of whether the products excluded under FSIS Notice 80-05 should be included in the *E. coli* O157:H7 testing program, or should continue to be excluded. FSIS officials were not able to provide us with any studies or test results to substantiate the agency's position that only certain raw ground beef products were of sufficient risk to warrant testing. Therefore, we believe that FSIS should perform scientific studies to determine whether the risk of *E. coli* O157:H7 outbreaks from non-hamburger or bulk ground beef products is sufficiently low as to warrant their continued exclusion from the testing program.

Recommendation 6

Perform scientific studies to determine whether the risk of *E. coli* O157:H7 outbreaks from excluded raw ground beef products is sufficiently low as to warrant their continued exclusion from the testing program.

Agency Response

According to their response, FSIS has sufficient science-based input from the National Advisory Committee on Microbiological Criteria for Foods to guide its approach to ensuring that the risk associated with *E. coli* O157:H7 in various ground beef components is being properly managed. Moreover, the agency has clearly articulated its intent to further assess proper controls for *E. coli* O157:H7 in source materials used to make ground beef, as well as for making other non-intact products (including meatballs and sausage products) in recent Federal Register documents. By early November 2006, FSIS expects to issue an FSIS Notice containing instructions for the routine testing of manufacturing trim in establishments that have been identified as suppliers impacted in positive tests for *E. coli* O157:H7. FSIS believes that this testing of manufacturing trim is a more science- and risk-based approach to ensuring that products made from beef are safe, rather than diverting limited resources for sampling non-ground beef end-products (e.g., sausage and meatballs).

OIG Position

We accept FSIS' management decision. Final action can be reached on the issuance of the notice.

Scope and Methodology

We performed audit work at FSIS Headquarters in Washington D.C., and at the District 50 Office in Lombard, Illinois. We also visited 11 judgmentally-selected meat and poultry establishments located in Illinois. We performed our fieldwork from June 2005 through June 2006.

At FSIS Headquarters, we held discussions with officials from OPHS, OFO, and the Information Technology (IT) staff. We reviewed both standard and ad hoc PREP reports to identify the controls and procedures in place to ensure that (1) meat and poultry establishments were properly identified for inclusion in the sampling frames for each testing program; (2) establishments were scheduled for sampling within reasonable timeframes; and, (3) district office personnel provided proper oversight of the process to collect scheduled samples.

At the district office and selected establishments, we performed tests to evaluate the operation of these controls and processes at the field level. We reviewed PBIS Plant Profile information as well as the eADRS system on each establishment whose products appeared eligible for *Salmonella* testing, to identify establishments that may have been excluded; we provided this information to the district office for followup. Based on these results we obtained equivalent information for all establishments nationwide, and provided the results of our evaluation to OPHS for followup. We also held discussions with employees of the Illinois Department of Agriculture to evaluate controls over State-inspected establishments operating under Federal-State Cooperative Agreements. We reviewed data from PREP reports that tracked the disposition of sampling requests for this district and two others, to evaluate the effectiveness of FSIS' controls to ensure compliance by FSIS establishment inspectors. At the meat and poultry establishments, we observed operations and reviewed PBIS profile information to perform comparisons with data maintained in the PREP system. We did not, however, perform sufficient reviews of PBIS to comment on the accuracy of the establishment profile information.

The audit was conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States.

***Salmonella* Sampling Set**

Chicago District Office

Sampling Set per FSIS	Questionable Estblshmts. Identified by OIG	Estblshmts. Added by District	Percent Excluded
99	75	39	28%

Remaining Districts

District	Sampling Set per FSIS		Additional Estblshmts. Identified by OIG for Potential Inclusion
05	118		116
15	156		101
20	57		52
25	56		43
30	80		32
35	49		18
40	66		53
45	96		17
60	173		85
65	203		84
75	57		42
80	77		56
85	121		69
90	73		22
Total	1,382		790

Potentially Excluded

Sampling Set Per FSIS of 1,382 x Rate of Exclusion 1.39 = 1,921

No. Possibly Excluded – 539

Summary of 39 Establishments Questioned by Type of Establishment and Product

Type of Establishment	
Processing	29
Slaughter	5
Combination	5
Total	39

Type of Product	
Ground Beef	27
Ground Chicken	1
Ground Turkey	1
Slaughter – Hogs	2
Slaughter – Steers/Heifers/Hogs	3
Combo – Slaughter Steers/Heifers/Hogs/ Ground Beef	5
Total	39

Exhibit C – Potentially Eligible Establishments Not Included in Nationwide HACCP (HC01) Sampling Frame (Excluding District 50)

Type of Establishment	
Processing	714
Slaughter	40
Combination	36
Total	790

Type of Product	
Ground Beef	530
Ground Chicken	147
Ground Turkey	37
Slaughter – Chicken	12
Slaughter – Chicken/ Guinea	3
Slaughter – Dairy Cows/ Beef cows	1
Slaughter – Hogs	6
Slaughter – Steers	1
Slaughter – Steers/ Heifers	6
Slaughter – Steers/ Heifers/ Hogs	11
Combo – Slaughter Chicken/ Ground Chicken	2
Combo – Slaughter Hogs/ Ground Beef	1
Combo – Slaughter Steers/ Ground Beef	1
Combo – Slaughter Steers/ Heifers/ Ground Beef	2
Combo – Slaughter Steers/ Heifers/ Hogs/ Ground Beef	30
Total	790

United States Department of Agriculture | Food Safety and Inspection Service | Washington, D.C. 20250

SEP 26 2006

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

FROM: Barbara J. Masters, D.V.M. Barbara Masters
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – Review of Pathogen Reduction Enforcement Program (PREP) Sampling Procedures

We appreciate the opportunity to review and comment on this report. The Food Safety and Inspection Service (FSIS) has reviewed the draft report with great interest and has responded to each of the six audit recommendations.

Recent Agency data had shown a persistent upward trend in the percentage of broiler (young chicken) samples positive for *Salmonella*. This is of concern to the Agency, particularly because of the associated increased exposure of the public to serotypes of *Salmonella* that are commonly associated with human illness. Therefore, since the beginning of this audit, FSIS has taken a number of actions to enhance public health protection by redirecting its *Salmonella* verification sampling program. Other product classes have not shown such a persistent upward trend, and the percentage of positive verification samples has declined for all three beef product classes. For these reasons, FSIS concluded that it needed to redirect its *Salmonella* verification sampling program to ensure that it is useful in providing enhanced public health protection. FSIS announced several steps to increase public health protection in a Federal Register Notice on February 27, 2006 (Vol. 71, No. 38, 9774). FSIS announced changes in how it uses the results from its *Salmonella* verification sampling program for meat and poultry establishments, and changes in how it reports these results. FSIS also provided a new compliance guideline for industry that encourages establishments to reduce levels of *Salmonella* during poultry slaughter operations using best management practices.

In addition to the responses to the audit recommendations, FSIS would like to offer additional comments for clarification. The report states that controls still need to be materially strengthened within the *Salmonella* testing program to ensure that all eligible establishments are included as required and that OIG identified a number of establishments that appeared eligible for the *Salmonella* sampling program, but were inadvertently not included in the database. The report qualifies that finding by correctly stating that some of these establishments should not be included because their processing is too infrequent, but it is also important to note firms may not be eligible for the *Salmonella* sampling program because they may not produce a product subject to testing. Also, although the report focused on the *Salmonella*, Ready-to-Eat (RTE), and *E. coli* O157:H7 sampling programs, it is also important to note that FSIS has established a variety of testing projects for testing on an "as

needed" basis. These projects include intensified product verification testing, intensified contact surface sampling, intensified non-contact surface sampling, and follow-up or targeted sampling as requested by field personnel.

1. Recommendation 1
Issue guidance to more clearly state the responsibilities of field personnel in assuring the *Salmonella* sampling frame includes all establishments eligible for testing.

Agency Response
The Office of Policy, Program and Employee Development (OPPED) will form a multi-program area team to develop an FSIS Notice that gives explicit instructions to District Managers to update the PREP *Salmonella* sampling frame. Eligibility requirements for the *Salmonella* sampling frame will be included and will reflect the recently published "FSIS Scheduling Criteria for *Salmonella* Sets in Raw Classes of Product" which outlines Agency policy to allocate sampling within classes of raw product and is based on Agency data of the variability of process control at individual establishments.

Agency data show that those establishments performing well are likely to continue to have a lower percentage of positive results. Conversely, establishments with higher percent positive results show much greater variability and inconsistency in their sample results. Most establishments with higher percent positive results maintain an elevated average percentage of positive *Salmonella* samples until FSIS conducts a food safety assessment and identifies food safety system design and execution weaknesses to the establishments. For these reasons, and others, FSIS has concluded that it needed to re-direct its *Salmonella* verification sampling program to ensure that it is useful in providing enhanced public heath protection.

In a *Federal Register* Notice issued February 27, 2006, FSIS announced several steps to increase public health protection. Completed *Salmonella* sample set results will be used to classify classes of raw products at establishments into one of three categories in relation to the standard or baseline guidelines (i.e. consistent, variable, or highly variable process control). The "FSIS Scheduling Criteria for *Salmonella* Sets in Raw Classes of Product" establishes scheduling criteria based on these three process control classifications. FSIS believes that targeting its *Salmonella* sampling according to these categories will enable it to maximize the effective use of its resources.

In addition to the steps mentioned above, FSIS is adding results from individual *Salmonella* verification sample tests to reports the Agency regularly makes to meat and poultry establishments that have asked to be informed of various test results. These *Salmonella* sample results are being sent to establishments as soon as they become available. FSIS had previously only reported *Salmonella* test results to an establishment only when a sample set is completed.

Completion Date: December 2006.

2. Recommendation 2
Modify the Performance Based Inspection System (PBIS) to incorporate the coding necessary to identify establishments requiring *Salmonella* testing similar to those already presently used for the *E. coli* O157:H7 and *Listeria monocytogenes* testing programs.

Agency Response
A production volume PBIS profile extension is currently being piloted, and can provide data on the production of raw ground beef and poultry that can be used to update the *Salmonella* sampling frame. The *Salmonella* Eligibility Reports are no longer being sent to the districts (last time was in February 2006). An FSIS notice has been drafted to inform the districts that they will no longer receive the eligibility report, and that the *Salmonella* sampling frame will be derived from electronic Animal Disposition and Reporting System (eADRS) data and the production volume profile extension data. Instructions are provided for identifying new establishments or establishments that begin making an eligible product, and getting them added to the frame.

Completion Date: March 2007.

3. Recommendation 3
Use eADRS to the extent necessary to ensure that all establishments eligible for *Salmonella* testing are included in the sampling frames.

Agency Response
To ensure that all establishments eligible for testing are included in the *Salmonella* sampling frames, the frames will be derived from eADRS data and the production volume profile extension data from PBIS which is currently being piloted. The Agency began using eADRS data to identify establishments slaughtering species for which there is a performance standard or guideline in May 2005.

Completion Date: March 2007

4. Recommendation 4
Provide written procedures to all district offices, to ensure that processes for identifying establishments that need to be tested for *Salmonella* are supplied to Talmadge-Aiken establishments.

Agency Response
OPPED will form a multi-program area team to develop an FSIS Notice that gives explicit instructions to District Managers to update the PREP *Salmonella* sampling frame. Eligibility requirements for the *Salmonella* sampling frame will be included and will reflect the recently published "FSIS Scheduling Criteria for *Salmonella* Sets

3

in Raw Classes of Product" which allocates sampling within classes of raw product based on variability of process control.

Completion Date: December 2006

5. Recommendation 5
Develop a risk assessment to support the Agency's policy in excluding establishments from *Salmonella* testing or conduct testing in all plants.

Agency Response
Product produced by plants not included in the *Salmonella* testing program represents a fraction of a percent of consumer exposure to *Salmonella* from raw meat and poultry. The Agency believes consumer exposure is minimal from the establishments which are not tested. FSIS does not believe it is a good use of Agency resources to perform the suggested risk assessment.

In the risk-based system approach that FSIS is developing, exposure of food safety hazards to the public is related to production volume. FSIS is taking steps, through the response to Recommendation 1 for ensuring that eligible plants are included in the *Salmonella* sampling frame and that limited Agency resources are properly managed by allocating sampling based on Agency data of the variability of process control at individual establishments

Completion Date: December 2006

6. Recommendation 6
Perform scientific studies to determine whether the risk of *E. coli* O157:H7 outbreaks from excluded raw ground beef products is sufficiently low as to warrant their continued exclusion from the testing program.

Agency Response
FSIS has sufficient science-based input from the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) to guide its approach to ensuring that the risk associated with *E. coli* O157:H7 in various ground beef components is being properly managed (see "NACMCF Response to USDA/FSIS Request for Guidance on Baseline Study Design and Evaluations for Raw Ground Beef Components," September 30, 2003).

Moreover, the Agency has clearly articulated its intent to further assess proper controls for *E. coli* O157:H7 in source materials used to make ground beef, as well as for making other non-intact products (including meatballs and sausage products) in recent Federal Register documents (see Federal Register Vol. 64, No. 11, 2803, and Federal Register Vol. 67, No. 194, 62325). FSIS stated that its regulatory testing program would be modified to begin testing manufacturing trim. FSIS first needed to initiate a

nationwide trim baseline which is set to end in late fall 2006. As a next step, by early November 2006, FSIS expects to issue an FSIS Notice containing instructions for the routine testing of manufacturing trim in establishments that have been identified as suppliers implicated in positive tests for *E. coli* O157:H7. FSIS believes that this testing of manufacturing trim is a more science- and risk-based approach to ensuring that products made from beef are safe, rather than diverting limited resources for sampling non-ground beef end-products (e.g., sausage and meatballs). More effective controls for this pathogen at a point in the distribution chain as early as possible before further processing, presents a greater opportunity for preventing adulterated product from getting into commerce than does end-product testing.

Completion Date: November 2006

If you have any questions, please contact William C. Smith, Assistant Administrator, Office of Program Evaluation, Enforcement and Review, at (202) 720-8609.

5